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Current concepts in otitis media

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This issue of *Pediatric Review* is intended for pediatricians, family physicians and all other interested medical professionals. For CME purposes, the author has no relevant financial relationships to disclose.

Objectives

At the end of this activity the participant should be able to:

1. Explain the incidence and primary risk factors of otitis media
2. Describe the clinical presentation and management for children with otitis media
3. Discuss up-to-date theories about treating pediatric otitis media

Introduction

With the exception of the common cold, otitis media is the most common disorder for which children (and their families) seek pediatric care. The fiscal burden related to otitis is estimated to exceed $5 billion a year in the United States.

Otitis media is the most frequent bacterial infection of childhood and the most common indication for antimicrobial therapy in this age group. However, despite years of clinical experience with the disorder, the clinical management continues to evolve.

Presentation of otitis media

Otitis media is generally defined by the presence of effusion within the middle ear without reference to its cause or pathogenesis. Acute otitis media (AOM) is usually associated with the rapid onset of symptoms and signs of acute infection in the middle ear space, including fever, earache, inflammation or bulging of the tympanic membrane, and purulent middle ear effusion. However, there is no constellation of signs and symptoms that has been universally accepted in establishing this diagnosis. Otitis media with effusion (OME) is the presence of serous, mucoid, or mucopurulent fluid in the middle ear without acute symptoms (fever, earache).

The pathogenesis of otitis media is multifactorial, including infection, impaired eustachian tube function, immature immune status and allergy. In most cases, otitis media begins with a viral infection of the upper respiratory tract that causes congestion of the eustachian tube and impairment of normal eustachian tube function, including middle ear ventilation, ciliary clearance and drainage. Effusions may also occur in the absence of infection, typically in ears in which negative pressure caused by transiently or chronically impaired eustachian tube function, resulting in atelectasis and retraction of the tympanic membrane and transudation of serous fluid into the middle ear.

Acute otitis media is primarily a disease of infancy and early childhood, with the peak age-specific attack rate occurring between six and 18 months of age. Risk factors for otitis media have been established by numerous investigators, with the most significant including attendance at group day care (larger day care size associated with higher relative risk), sibling history of recurrent otitis media, early occurrence of initial otitis media, and lack of breastfeeding. Male gender, allergy, pacifier use, exposure to cigarette smoke, heredity and lower socioeconomic status have also been implicated, but their relative risk is lower or less consistently established.

The bacterial species involved in AOM have not changed significantly over the last two decades. Streptococcus pneumoniae continues to be the most prominent pathogen, accounting for approximately 40% of cases. The other two most common organisms are Haemophilus influenzae and Moraxella catarrhalis.

Diagnosis of AOM cannot be made on the basis of symptoms alone. Although earache has a specificity of 82 to 92%, its sensitivity is only 54 to 60%. Rubbing the ears, restlessness and fever are even less reliable, and no particular constellation of symptoms is predictive. Diagnosis of middle ear effusion is more reliably made on the basis of pneumatic otoscopy and tympanometry. Examination by a trained otoscopist achieves a sensitivity of 81 to 94% and a specificity of 74 to 93% when compared with findings at myringotomy.

The advent of antibiotic therapy in the mid-20th century brought a tremendous downturn in the incidence of complications of AOM. Treatment with antibiotics rapidly became the standard of care in the United States and other developed countries. However, the development of bacterial resistance, expense and the potential for side effects have led clinicians to reconsider the need for medical intervention. The natural history of an individual episode of AOM is quite favorable. In observational studies and randomized clinical trials, 70 to 90% of children with AOM treated with placebo or no drug demonstrated spontaneous clinical resolution in 7 to 14 days. Most advocates of watchful waiting in the United States still recommend antimicrobial therapy for children younger than 2 years.

Surgery for recurrent AOM should be recommended only for patients with severe symptoms and a history of at least three or four episodes in a 6-month period, anticipating at best a modest reduction

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Clinical Practice Guideline for the Management of Otitis Media with Effusions	
STRONG RECOMMENDATIONS	**RECOMMENDATIONS**
Document: Laterality of effusion (left, right or both ears) Duration of effusion Presence and/or severity of associated symptoms	Hearing testing for effusions ≥ 3months or Hearing test for speech or learning problems or Hearing test for concern of hearing loss
Identify child with OME at risk for speech, language and/or learning problems	Reexamine patient with asymptomatic and non-pathologic OME every 3 – 6 months
Manage asymptomatic and non-pathologic OME with watchful waiting for 3 months	When tubes are indicated, adenoidectomy is not recommended unless there is a distinct indication such as chronic nasal obstruction or adenoiditis. Adenoidectomy is indicated if a second set of tubes is needed.

Table 1. Treatment Guidelines for OME (adapted from Schraff18)

in the frequency of infection. Both objective and subjective quality of life measurements have demonstrated significant benefit in children appropriately treated with insertion of tympanostomy tubes.

OME is a relatively asymptomatic process. As a result, management is initiated with two goals in mind: restoration of normal hearing and avoidance of middle ear sequelae. OME is associated with conductive hearing loss causing an average threshold elevation of 25 to 30 dB. Children often present with complaints of difficulty hearing the telephone or television, or with teacher concerns of inattentiveness in class, and data suggest that OME is associated with reduced speech recognition in competing noise.

Clinical evidence seems to suggest the following:

1. Speech reception and production have been inadequately studied, particularly in preschool-age children. Some results imply that prolonged early OME may be associated with more speech errors in children of school age.
2. Persistent, early OME seems to have some adverse effect on language development during the early preschool period. Expressive language is more likely to be affected than receptive skills.
3. Available trials regarding effects of OME on cognition are sparse and yield conflicting results.
4. Behavioral studies consistently suggest that children with prolonged OME are more easily distracted and less attentive, with effects potentially extending to early school age and teenage years.

Otitis media with effusion may result from resolving AOM or may arise because of eustachian tube dysfunction. After an episode of untreated AOM, spontaneous clearance of OME may be expected in approximately 75% of children within three months; with treatment of the acute episode, clearance at three months may be as high as 90%. Meta-analysis of blinded clinical trials suggests a mild improvement in clearance rates of approximately 15% with antibiotic therapy. As a result, it seems reasonable to treat an episode of OME with one course of antibiotics before consideration of tympanostomy tubes. Studies suggest that intranasal steroids may be useful as adjunctive therapy for short-term treatment of OME but offer no long-term protection against AOM or OME. There have been a few trials of other medical interventions for OME. Efficacy studies of antihistamines and decongestants have found these medications of no clinical benefit for treatment of OME. Table 1 is a summary of recent recommendations in the treatment of OME.

Tympanostomy tubes are a reasonable consideration in patients with at least 3 months of bilateral or 6 months of unilateral effusion, or in patients in whom a majority of the previous year was spent with middle ear disease. Patients with effusions for less time but who also have severe symptoms, severe hearing loss, or development of atelectasis or retraction packets should also be considered. Adenoidectomy may be reserved for the second set of tubes, but should be considered primarily in patients with a history of chronic nasal obstruction or adenoiditis.

When present, modifiable risk factors should be addressed with the patient's family. Tobacco exposure should be minimized. Day care exposure should ideally be limited to small group settings, and patients with suspected allergy should be evaluated and appropriately treated.

The heptavalent pneumococcal vaccine (Prevnar; Wyeth Pharmaceuticals, Philadelphia, PA) was approved by the Food and Drug Administration in 2000 for prevention of invasive infections caused by S. pneumoniae. However, it has resulted in only a modest reduction in incidence of otitis media. Current recommendations call for universal immunization of children younger than two years and selective vaccination of older children with significant risk factors for rAOM [73]. Vaccination against influenza with heat-killed and live attenuated virus has demonstrated a significant reduction in influenza-related otitis media.

Conclusions

Management of otitis media has become quite costly and increasingly difficult because of the emergence of resistant pathogens. Reduced medical and surgical therapy is indicated, particularly in light of the favorable natural history of the disorder and the low likelihood of significant effects on development in children. Preventive measures such as reduced day care attendance and size, limitation of tobacco exposure, and control of reflux and allergy are

imperative, and patients should be urged to follow through with current immunization recommendations.

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Children's Hospital implants first pediatric Berlin Heart in Louisiana

Device extends time three-year-old can wait for transplant

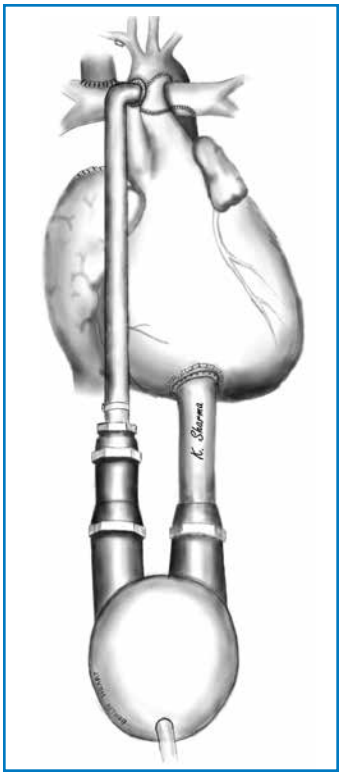
In early July, Erica Sanchez noticed her three-year-old daughter, Malia, began coughing, running low grade fever and turning a "greenish-yellow" color. After a trip to a walk-in clinic and the emergency room, it was revealed she had a Level 5 heart murmur. Doctors ran an EKG, which showed that her blood flow had diminished significantly. Malia was diagnosed with Cardiomyopathy, a deterioration of the heart muscle which usually leads to heart failure.

On Friday, July 13, they left home in Boyce, La., and came to Children's Hospital, where her condition deteriorated, and she coded. On Sunday, she was placed on Extracorporeal Membrane Oxygenation (ECMO), a machine which acts as a patient's heart and lungs for life support. ECMO is generally used for respiratory failure and short term cardiac failure. Because of her condition, she required support which was a little more complicated than ECMO could provide. Doctors at Children's Hospital determined that a Berlin Heart, a medical device that supports the weakened hearts of children with heart failure to help keep them alive until a donor for a heart transplant can be found, would be the only way she would survive long enough to get a donor heart transplant. The device comes in graduated sizes to fit children from newborns to teens.

According to the FDA, heart failure in children is much less common than in adults. Heart transplantation offers effective relief from symptoms. However, far fewer pediatric sized donor hearts are available for transplantation than for adults, limiting the use of heart transplantation in children and prolonging the waiting period until transplant can occur. In infants, the median waiting time for a donor heart is 119 days. Overall a reported 12 – 17% of children and 23% of infants die while on the wait list for a heart transplant.

"Pediatric patients on the list for a heart transplant can wait months because a heart must be of similar size," said Malia's pediatric cardiothoracic surgeon, Dr. Joseph Caspi. "This device keeps children alive while on the transplant list."

The Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD) is a mechanical cardiac support system for critically ill pediatric patients suffering from severe heart failure. The system is designed to support pediatric patients of all age groups, from newborns to teenagers, and is intended to bridge patients awaiting heart transplantation from days up to several months, until a donor heart becomes available. It was approved by the FDA in December 2011, as the only VAD that is designed specifically for pediatrics.



"Typically, ECMO is an excellent tool, but after seven to 10 days, if there is no recovery, other alternatives must be sought," Caspi said. "The other drawback is the need to keep the patient sedated and paralyzed. So, in this case, the best alternative was to use a VAD."

On Tuesday, July 24, 2012, Malia became the first child in Louisiana to be implanted with the device. Children's Hospital and LSUHSC pediatric cardiothoracic surgeons Caspi and Timothy Pettitt performed the six-hour open-heart surgery to attach tubes to her diseased heart in order for the device to pump blood from her heart through her body.

"The Berlin Heart is a pneumatic pump which is placed outside of the chest and connected to special tubes introduced into the left ventricle (inflow) and the aorta (outflow)," Caspi explained. "In the adult population, because of the size of the chest cavity, you can place an artificial heart inside of the chest. That is not the case with small children."

Because Children's Hospital does not currently have an active heart transplant program, her doctors chose to move Malia to Arkansas Children's Hospital in Little Rock, where she will be monitored by their heart team until she can receive a transplant.

"She only has the left ventricle. So she is still on lots of medication to keep her right heart happy and keep it putting blood through to the left ventricle which this device then pumps to her body," said Dr. Elizabeth Frazier, director of the cardiac transplant program at Arkansas Children's Hospital.

"There are reports of patients supported with the pump for 1,000 days," Caspi said. "The longest stay on the Berlin pump in North America was over a year, with an average duration of assisted device functioning for 76 days."

Malia and her mom are expected to live at Arkansas Children's Hospital for a year. Only time will tell how long the Sanchez family will have to wait for a new heart, but they expect to return home as a happy family.

Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD)

The Berlin Heart EXCOR Pediatric VAD is a blood pump designed to assist patients who cannot pump enough blood with their own natural heart. The device can be used in patients who cannot effectively pump blood with their left and/or right ventricle. The VAD device consists of one or two air-driven blood pumps (depending on single-ventricle or double-ventricle support), small tubes inserted into the body that are used to connect the blood pumps to the atrium or ventricle and to the great arteries, and the IKUS driving unit. The IKUS provides air pulses that drive the rhythm of the pumps and also has computer controls to be used by hospital staff.

How does it work? The EXCOR Pediatric VAD does not entirely replace the natural function of the heart. Instead, it works along with the patient's own heart to pump blood. In a healthy heart, the left ventricle pumps blood rich with oxygen (oxygenated) to the vital organs and the right ventricle pumps non-oxygenated blood to the lungs to obtain oxygen. In a heart weakened by heart failure, the left and/or right ventricles are not strong enough to pump blood sufficiently. The VAD helps the heart by supporting the weak ventricles.

The blood pump interior is divided into an air chamber and a blood chamber by a flexible membrane. Air pressure provided by the IKUS driving unit causes the membrane inside the pump to inflate and deflate. The air pulse moves the membrane, thus allowing blood to enter and exit the device. Valves are located at the blood pump connection branches to ensure one-way directional blood flow. The pulse rate and pump pressures can all be monitored and adjusted on the IKUS driving unit by hospital staff.

When is it used? The EXCOR Pediatric VAD is used when the natural heart is unable to maintain normal blood flows and/or pressure or if it cannot adequately provide oxygenated blood to the vital organs. It is intended to provide support to the heart while these pediatric patients await a heart transplant.

What will it accomplish? In the U.S clinical trial of a total of 48 patients, 43 out of the 48 patients (approximately 90%) survived to cardiac transplantation or were successfully taken off the device (because their hearts recovered). Of these 43 patients, 35 out of the 43 patients (greater than 70%) received a heart transplant or were taken off the device with either: a) no neurologic events (such as a clot blocking a blood vessel in the brain); or b) neurologic events that resulted in good neurologic outcomes (no apparent effect on normal brain function as a result of an event such as a clot blocking a blood vessel in the brain).

Children's Hospital Specialty Clinics & Therapies

CLINICS IN NEW ORLEANS, METAIRIE, BATON ROUGE AND LAFAYETTE

Allergy/Immunology
Dimitriades, Victoria [M, BR] ..... (504) 896-9589
Ochoa, Augusto [M] ..... (504) 896-9589
Paris, Ken [M, L] ..... (504) 896-9589
Sorensen, Ricardo [M] ..... (504) 896-9589

Amputee Clinic
Gonzales, Tony ..... (504) 896-9569

Cardiology
Ascuitto, Robert ..... (504) 896-9751
Gajewski, Kelly ..... (504) 896-9751
Lilje, Christian ..... (504) 896-9751
Ross-Ascuitto, Nancy ..... (504) 896-9751
Sernich, Steffan ..... (504) 896-9751
Siwik, Ernest ..... (504) 896-9571
Stopa, Aluizio ..... (504) 896-9571

Cardiothoracic Surgery
Caspi, Joseph ..... (504) 896-3928
Dorotan, Jaime ..... (504) 896-3928
Pettitt, Timothy ..... (504) 896-3928

Children at Risk Evaluation (CARE) Center
Jackson, Jamie ..... (504) 896-9237
Wetsman, Ellie ..... (504) 896-9237

Cleft/Craniofacial
McBride, Lori ..... (504) 896-9568
Moses, Michael ..... (504) 896-9857
St. Hilaire, Hugo ..... (504) 896-9857

Clinical Trials ..... (504) 894-5377

Cochlear Implants
Arriaga, Moises ..... (504) 896-2141
Marks, Herbert ..... (504) 896-2141

Craniofacial/Genetics
Lacassie, Yves [M] ..... (504) 896-9857
Marble, Michael ..... (504) 896-9857
Zambrano, Regina ..... (504) 896-9857

Cystic Fibrosis
Levine, Stephen ..... (504) 896-9436
Pepiak, Derek ..... (504) 896-9436

Dental
Mobile Dental Program 34-BRUSH
Ritwik, Priyanshi ..... (504) 896-9580

Dermatology
Poole, Jeffrey ..... (504) 896-2888

Developmental/High Risk
Wong, Joaquin ..... (504) 896-9458

Diabetes
Chalew, Stuart ..... (504) 896-9441
Genet, Michelle [BR] ..... (504) 896-9441
Gomez, Ricardo ..... (504) 896-9441
Stender, Sara ..... (504) 896-9441
Vargas, Alfonso ..... (504) 896-9441

Down Syndrome
Lacassie, Yves [M] ..... (504) 896-9254
Marble, Michael ..... (504) 896-9254
Zambrano, Regina ..... (504) 896-9254

Endocrinology
Chalew, Stuart ..... (504) 896-2888
Gomez, Ricardo [M, BR] ..... (504) 896-2888
Stender, Sara ..... (504) 896-2888
Vargas, Alonso [M, BR] ..... (504) 896-2888

Epilepsy Surgery
McGuire, Shannon ..... (504) 896-9458

Feeding Clinic
Hyman, Paul ..... (504) 896-9534

Gastroenterology
Brown, Raynorda [M, BR] ..... (504) 896-2888
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Keith, Brent ..... (504) 896-2888
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Noel, Adam [M] ..... (504) 896-2888
Rosenberg, Allan [M, BR] ..... (504) 896-2888

Genetics
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Marble, Michael [BR, L] ..... (504) 896-9254
Zambrano, Regina [M, BR] ..... (504) 896-9254

Gynecology
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Hematology/Oncology
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Morales, Jaime [BR, L] ..... (504) 896-9740
Morrison, Cori ..... (504) 896-9740
Prasad, Pinki [L] ..... (504) 896-9740
Ramos, Ofelia ..... (504) 896-9740
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Wilcox, Ronald ..... (504) 896-9583

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Referrals ..... (504) 896-3924
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Sulton-Villavasso, Carmen ..... (504) 896-3924

Infectious Disease
Bégué, Rodolfo ..... (504) 896-9583
Seybolt, Lorna ..... (504) 896-9583
Wilcox, Ronald ..... (504) 896-9583

International Adoption Clinic
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Paramesh, Anil ..... (504) 896-9238
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Kidney Transplant Clinic
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Marble, Michael ..... (504) 896-9254

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Weimer, Maria ..... (504) 896-9283
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Weimer, Maria ..... (504) 896-9859
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Ophthalmology
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Marks, Herbert ..... (504) 896-9254
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Kamps, Jodi ..... (504) 896-7272

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Pepiak, Derek ..... (504) 896-9438

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Gedalia, Abraham [M, BR, L] ..... (504) 896-9385

Scoliosis/Pediatric Spine
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Gonzales, Tony [BR] ..... (504) 896-9569
King, Andrew ..... (504) 896-9569
Patel, Prerana ..... (504) 896-9569

Spasticity
Nadell, Joseph ..... (504) 896-9568
Tilton, Ann ..... (504) 896-9283
Wong, Joaquin ..... (504) 896-9283

Speech & Hearing ..... (504) 896-9551

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Steiner, Rodney ..... (504) 896-9756
Valerie, Evans ..... (504) 896-9756

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Seybolt, Lorna ..... (504) 896-9583
Wilcox, Ronald ..... (504) 896-9583

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Ortenberg, Joseph [BR, L] ..... (504) 896-2888
Roth, Christopher ..... (504) 896-2888

Vascular Anomalies
Poole, Jeffrey ..... (504) 896-9857
Simon, Lawrence ..... (504) 896-9857

Wound Clinic
Valerie, Evans ..... (504) 896-3977

TRANSPORT/TRANSFER
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In addition to Children's Hospital Main Campus, some physicians also hold clinics at other centers.

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1. Acute otitis media (AOM) presents with the rapid onset of symptoms and signs of acute infection in the middle ear space, including fever and earache, while Otitis media with effusion(OME) presents with serous, mucoid or mucopurulent fluid in the middle ear without acute symptoms (fever, earache).
   a. True
   b. False

2. AOM is primarily a disease of:
   a. newborns, with peak attack rate between birth and 6 months of age
   b. infancy and early childhood, with peak attack rate between 6 and 18 months of age
   c. toddlers, with peak attack rate between 18 and 36 months of age
   d. childhood, with peak attack rate between 36 and 60 months of age

3. Observational studies and randomized clinical trials have shown AOM to clear up in ___% of children without use antibiotics.
   a. 0 – 25
   b. 25 – 40
   c. 40 – 60
   d. 70 – 90

4. Most advocates of watchful waiting in the United States still recommend antimicrobial therapy for children younger than ____.
   a. 6 months
   b. 1 year
   c. 2 years
   d. 3 years

5. Children with OME often present with complaints of difficulty hearing the telephone or television, or with teacher concerns of inattentiveness in class.
   a. True
   b. False

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